

Initiator Pharma completes dosing and last subject last visit in the IPTN2021 program Phase I study to assess pain-reducing effects

Initiator Pharma A/S, a clinical-stage pharma company, announced today that all planned subjects have had the last visit in Clinical part in the IPTN2021 program clinical Phase I study in healthy subjects challenged with the pain-inducing ingredient (capsaicin).

All planned clinical activities for the 24 healthy male subjects have taken place in Initiator Pharma's Phase I study in the IPTN2021 program that aims to target the treatment of trigeminal neuralgia. The study is a randomized, double-blind, 4-way crossover placebo-controlled study to investigate the pharmacodynamic effects of IP2015 using the intradermal capsaicin model. This study design is representative of both peripheral and neuropathic pain and constitutes an important evaluation of the pain relief properties of IP2015 before embarking on the following clinical study. The study is carried out in collaboration with MAC Clinical Research, UK, as a single site study. The obtained clinical data will now be undergoing data management, quality and statistical analysis. The data analysis will be related to the pain biomarkers collected, explore pharmacodynamic signals related to neuropathic pain and support future study designs related to trigeminal neuralgia pain. The first results are expected end of second quarter of 2022.

"I'm very pleased that we have been able to complete the in-life phase in this exploratory Phase I trial in a relative expedite manner. This is the first clinical trial in our IPTN2021 program using the drug substance IP2015 to treat pain. The trial will provide important pain related efficacy, biomarker and safety information to support the planned clinical development of IP2015. We are looking forward to receiving the data and use it to design the next clinical study aimed at the orphan drug pain indication trigeminal neuralgia." says Claus Elsborg Olesen, CEO of Initiator Pharma.

IP2015

IP2015 is the drug substance used in the Phase I study in the IPTN2021 program. IP2015 has previously shown proof of concept in erectile dysfunction. It is a monoamine reuptake inhibitor that preferentially inhibits dopamine and serotonin reuptake, thereby blocking pain sensation. IP2015 is superior to duloxetine in the rat formaldehyde pain model and the rat sciatic chronic constriction injury (CCI) model. Moreover, the safety of IP2015 is superior to duloxetine, and preclinical data showed no risk for drug interactions.

IP2015 is also the active pharmaceutical ingredient used in the IPED2015 program, which is currently undergoing Phase IIb testing in 120 patients for organic erectile dysfunction.

About neuropathic pain and trigeminal neuralgia

The clinical program IPTN2021 targets the orphan neuropathic pain indication trigeminal neuralgia, a rare disease with a prevalence of 10-20 per 100,000. Trigeminal neuralgia is a debilitating orofacial pain condition characterized by sudden onset of an extreme, short-duration yet debilitating pain, often referred to as suicidal pain. There is only one FDA-approved pharmacological treatment for trigeminal neuralgia available, Carbamazepine, which only provides limited pain relief and is associated with a significant number of side effects. Therefore, the unmet need for a new efficacious, tolerable, and safe treatment is exceptionally high. Initiator Pharma's ambition is to develop a First-Line treatment for these patients.

For additional information about Initiator Pharma, please contact:

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About Initiator Pharma

Initiator Pharma A/S is a Danish clinical stage life science company developing innovative drugs that target key unmet medical needs within the central and peripheral nervous system. Initiator Pharma's pipeline consists of three clinical programs - the drug candidates IP2018 and IPED2015 for treatment of erectile dysfunction of psychogenic and organic origin, respectively, and the orphan drug candidate IPTN2021 developed for Trigeminal Neuralgia, a severe neuropathic pain condition.

Initiator Pharma is listed on Nasdaq First North Growth Market (ticker: INIT). Redeye AB, with email address certifiedadviser@redeye.se and phone number +46 8 121 576 90, is the company's Certified Adviser. For more information, please visit www.initiatorpharma.com.

Attachments

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